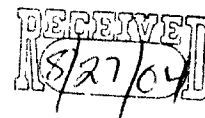




Monday, August 23, 2004

Ortho Molecular Products Inc.
3017 Business Park Drive
PO Box 1060
Stevens Point, WI 54481
715 342 9881 Phone
800 332 2351
715 342 9866 Fax
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached label).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: Prostatrol Forte Premier Men's Health Supplement

Dietary Ingredients: Zinc (as Chelazome Amino Acid Chelate), Selenium (as Amino Acid Complex), Copper (as Lysinate), Saw Palmetto Fruit Extract (Standardized to contain 45 – 55% Fatty Acids), Nettles Root Extract (Standardized to contain 30ppm Scopoletin), Pygeum Bark Extract (Standardized to contain 25% Phytosterols), Ascorbyl Palmitate, Microcrystalline Cellulose, and Silicon Dioxide.

Dietary Supplement Name: Prostatrol Forte

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Deborah Zurawski 8-23-04

Deborah Zurawski
Quality Assurance Manager
Ortho Molecular Products

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SUGGESTED USE: As a dietary supplement, 1-2 capsules per day or as recommended by your health care professional.

Formulated to be free of the following: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep out of reach of children. This product was sealed for your protection. Do not use if outer topped neck seal or inner seal are missing or damaged.

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Microcrystalline Cellulose and Silicon Dioxide. Chelazome® is a registered trademark of Albion, Inc. Mfg. by Ortho Molecular Products Inc. 3017 Business Park Drive, Stevens Point, WI 54481.

OrthoMolecularProducts.com
Label ID: L-OMP100-519060-B



**PROSTATROL
FORTE**
PREMIER MEN'S HEALTH SUPPLEMENT

Supplement Facts		Amount Per	% Daily
Serving Size 1 Capsule	Serving	Value	
Servings Per Container 60			
1 capsule contains			
Zinc	8 mg	53%	
(as Chelazome® Amino Acid Chelate)			
Selenium (as Amino Acid Complex)	50 mcg	71%	
Copper (as Lysinate)	500 mcg	25%	
Saw Palmetto Fruit Extract	300 mg		
(Standardized to contain 45-55% Fatty Acids)			
Nettles Root Extract	120 mg		
(Standardized to contain 30ppm Scopoletin)			
Pygeum Bark Extract	50 mg		
(Standardized to contain 25% Phytosterols)			
* % Daily Value not established			